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10/533,539	05/02/2005	Katsuya Togawa	M&M-079-USA-PCT	1593

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EXAMINER	
DIRAMIO, JACQUELINE A	
ART UNIT	**PAPER NUMBER**
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,539	TOGAWA ET AL.	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-5,9,10 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-8,11-15 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 August 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

Applicant's amendments to claims 6 and 14 and addition of new claim 20 are acknowledged.

Currently, claims 6 – 8, 11 – 15 and 17 – 20 are pending and under examination. Claims 1 – 5, 9, 10, and 16 are acknowledged as withdrawn as drawn to non-elected inventions.

Withdrawn Objections and Rejections

The previous objections to claims 6 and 14 are withdrawn in view of Applicant's amendments filed February 20, 2008.

All previous claim rejections under 35 U.S.C. 103 are withdrawn, as well as the finality of the rejections, in view of Applicant's arguments filed February 20, 2008.

Response to Arguments

Applicant's arguments, see p7-10, filed February 20, 2008, with respect to the rejection(s) of the claim(s) under 35 U.S.C. 103 as being unpatentable over Kitajima et al. (US 5,876,605) in view of Kadoya (US 4,976,858) have been fully considered and are persuasive. Applicant's argument that Kitajima et al. fail to teach that the microporous (plasma or serum separating) membrane has a porosity of not more than 30% is found persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made and presented below.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6 – 8, 14, 15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima et al. (US 5,876,605) in view of Kadoya (US 4,976,858) and Matsuda et al. (US 4,409,339).

Kitajima et al. teach a filter unit 1 (apparatus) comprising:

a first filter member 10 through which plasma can move faster than corpuscles, said first filter member having an upstream and downstream part; and

a microporous (plasma or serum separating) membrane 13 being serially connected in a subsequent stage with the first filter member (see Figure 1; column 1,

lines 58-64; column 2, lines 45-62; column 5, lines 46-52; column 6, lines 1-27; column 9, lines 14-20; and Example 1).

However, Kitajima et al. fail to teach that the first filter member has a packing density of a downstream part higher than a packing density of an upstream part in the filter member, or that the microporous (plasma or serum separating) membrane has a porosity of not more than 30%.

Kadoya teaches a filter medium that comprises a nonwoven fabric of a lower density and a filter paper of a higher density, wherein the nonwoven fabric and the filter paper are superposed in a laminated structure, and the nonwoven fabric and the filter paper are disposed upstream and downstream, respectively. The nonwoven fabric 5 and filter paper 2 are placed as a layer, one on top of the other, and thermally fused together to form a single filter medium 1. The nonwoven fabric has a relatively low fiber density in the range of 0.15 to 0.25 g/cm^3, and the filter paper has a relatively high fiber density in the range of 0.2 to 0.3 g/cm^3. The benefit of creating a filter medium that contains a low fiber density fabric that is first contacted with the fluid to be filtered followed by a higher density filter paper is that it allows for effectively trapping relatively larger particles contained in the fluid by the entrance surface of the filter medium, wherein such surface trapping may prevent the particles from being embedded with the filter medium, which prevents clogging of the filter medium (see Figure 1; column 1, lines 56-68; column 2, lines 1-24 and lines 60-68; column 3, lines 1-30; and column 6, lines 6-20).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with filter device of Kitajima et al. a first filter member that has an higher density downstream part and a lower density upstream part as taught by Kadoya because Kadoya teaches the benefit of creating a filter medium that contains a low fiber density fabric that is first contacted with the fluid to be filtered followed by a higher density filter paper in order to effectively trap relatively larger particles contained in the fluid by the entrance surface of the filter medium, wherein such surface trapping may prevent the particles from being embedded with the filter medium, which prevents clogging of the filter medium.

Matsuda et al. teach a porous membrane for filtering particles in an aqueous liquid, including the removal of corpuscles from blood. The porous membrane has an average pore diameter of 0.05 to 1 μ and a porosity in the range of 30% to 80%. Generally, the pore structure, average diameter of the pores and the porosity of a porous membrane have significant meanings, wherein the pore structure and average pore diameter have great influences on the removal capability of the membrane while the porosity has great influence on the water permeability, mechanical strength and elongation. In particular, a porous membrane with a porosity of less that 30% was found to have low water permeability but did possess an excellent mechanical strength and elongation (see column 1, lines 6-15; column 2, lines 62-68; column 3, lines 1-52; column 5, lines 36-46; column 7, lines 60-68; and Example 2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the membrane of Kitajima et al. to have a

particular porosity, such as not more than 30%, as taught by Matsuda et al. because Matsuda et al. teach the significance of the porosity of a porous membrane, wherein the porosity has great influence on the water permeability, mechanical strength and elongation of the porous membrane. In addition, Matsuda et al. teach the benefit of preparing a porous membrane with a porosity of less that 30% because this creates a membrane with low water permeability but with an excellent mechanical strength and elongation.

With respect to Applicant's claim 7, Kitajima et al. teach that the filter member serves as the first filter member 10 or 11, the microporous membrane 13 serves as a second filter member, and a third filter member 10 made of fiber having a mean fiber diameter of not less than 3.0 μm and a bulk density of about 0.02 to 0.3 g/cm^3 is provided upstream of the first filter member 10 or 11 (see Figure 1; column 5, lines 46-52; column 6, lines 1-27; and Example 1).

With respect to Applicant's claim 8, Kitajima et al. teach that the first filter member 10 is made of fiber, has a mean fiber diameter from 0.2 to 3.0 μm and a filled density from 0.02 to 0.3 g/cm^3 (see Figure 1; column 5, lines 46-62; and column 6, lines 1-4; and Example 1). Kadoya also teaches that the filter medium is made of fiber and has a filled density from 0.15 to 0.3 0.3 g/cm^3 (see column 3, lines 5-14).

With respect to Applicant's claim 14, Kitajima et al. teach that the device includes a sample intake 7 (blood accommodation part) provided upstream to the filter members, wherein an aqueous solution is added to the blood sample prior to adding the sample to

the intake and filtering the sample through the first and second filter members, wherein the solution has an osmotic pressure that prevents the rupturing of blood cells, particularly erythrocytes, or the puncturing of blood cell membranes (see column 3, lines 6-67; column 4, lines 1-49; and column 5, lines 22-52). Although Kitajima et al. fail to teach the specific range of the osmotic pressure for the aqueous solution as being 200 to 300 mOsm/kg, Applicant's specification discloses that the aqueous solution has an osmotic pressure of 200 to 350 mOsm/kg, which is the osmotic pressure which prevents the breakage of erythrocytes (see Applicant's specification p36). Therefore, the aqueous solution of Kitajima et al. would inherently have an osmotic pressure within Applicant's range because Kitajima et al.'s aqueous solution is also taught to contain an osmotic pressure that prevents the rupturing of blood cells, particularly erythrocytes, or the puncturing of blood cell membranes.

With respect to Applicant's claim 15, Kitajima et al. teach that the aqueous solution can contain an HL agent (internal substance) (see column 3, lines 6-67; column 4, lines 1-59; and column 5, lines 22-52).

With respect to Applicant's claims 18 and 19, Kadoya teaches that the filter medium is made of polyester-based resin (see column 2, lines 65-68; and column 3, lines 1-14).

Claims 11 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima et al. (US 5,876,605) in view of Kadoya (US 4,976,858) and Matsuda et al. (US 4,409,339), as applied to claim 6 above, and further in view of Ayres (US 3,891,553).

The Kitajima et al., Kadoya and Matsuda et al. references, which were discussed in the 103(a) rejection above, fail to teach that the first filter member has a property of absorbing fibrinogen contained in blood, plasma, or a fibrinogen solution.

Ayres teaches a serum and plasma separator comprising a container, a piston, and a filter means, wherein the filter means comprises a first filter member which will pass red blood corpuscles therethrough but will not pass fibrin and fibrous constituents of blood, and a second filter member which will pass the light phase of blood but which will not pass red blood corpuscles therethrough. Therefore, the first filter member is characterized to have pore sizes which allow for the passage of red blood cells, but will not allow the passage of particulate material, such as fibrin. Thus, the first filter member removes particles of fibrin and other particulate matter from an applied blood sample (see column 2, lines 3-39; and column 4, lines 2-50).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide with the first filter member of Kitajima et al., Kadoya and Matsuda et al. the property of absorbing fibrinogen as taught by Ayres because Ayres teaches the benefit of including a first filter member in a plasma or serum separating device that is characterized to have pore sizes which allow for the passage of red blood cells, but will not allow the passage of particulate material, such as fibrin, in order to effectively remove particles of fibrin and other particulate matter from an applied blood sample prior to the removal of red blood cells from the sample.

With respect to Applicant's claim 20, Kadoya teaches that the filter medium is made of polyester-based resin (see column 2, lines 65-68; and column 3, lines 1-14).

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima et al. (US 5,876,605) in view of Kadoya (US 4,976,858) and Matsuda et al. (US 4,409,339), as applied to claim 6 above, and further in view of Bell (US 2003/0206828).

Kitajima et al., Kadoya and Matsuda et al. further fail to teach that an anticoagulant compound is stored in at least a part of the internal space of the filter apparatus.

Bell teaches a whole blood sampling device comprising a tube having a self-filling capability and that includes a blood separation filter. The filter has a plurality of pores sized to permit passage of selected blood constituents, such as blood plasma, through the device. The tube can include an anti-coagulant reagent, preferably in dry form, dispensed throughout the interior of the tube, which prevents the clotting of blood contained within the tube, and further facilitates the flow of blood plasma from the tube through the filter (see Abstract; and paragraph [0012]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the filter unit of Kitajima et al., Kadoya and Matsuda et al. an anticoagulant component as taught by Bell because Bell teaches the benefit of including an anti-coagulant reagent in the interior of a blood sampling device in order to prevent the clotting of blood contained within the device, and further to facilitate the flow of blood plasma through a filter contained within the device.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima et al. (US 5,876,605) in view of Kadoya (US 4,976,858) and Matsuda et al. (US

4,409,339), as applied to claim 6 above, and further in view of Anraku (US 5,413,786).

Kitajima et al., Kadoya and Matsuda et al. fail to teach that an accelerator for accelerating coagulation of blood is stored in at least a part of the internal space.

Anraku teaches a method for accelerating blood coagulation by contacting blood with an accelerator comprising a metal complex. The addition of an accelerator for blood coagulation to a blood sample is beneficial because it gives a good separation effect between the serum and the blood clot, which allows for the separation of the serum from the blood clot in a high yield and without causing a change in the serum, so that the serum can be used for every kind of biochemical and clinical test (see Abstract; and column 3, lines 49-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the filter unit of Kitajima et al., Kadoya and Matsuda et al. an accelerator for accelerating coagulation of blood as taught by Anraku because Anraku teaches the benefit of adding an accelerator for blood coagulation to a blood sample because it gives a good separation effect between the serum and the blood clot, which allows for the separation of the serum from the blood clot in a high yield and without causing a change in the serum, so that the serum can be used for every kind of biochemical and clinical test.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kitajima et al. (US 5,876,605) in view of Kadoya (US 4,976,858) and Matsuda et al. (US 4,409,339), as applied to claim 6 above, and further in view of Chu (US 6,632,681).

Kitajima et al., Kadoya and Matsuda et al. fail to teach that the filter unit contains or stores a strip of immunochromatographical diagnostic agent to be added to the separated plasma or serum.

Chu teaches a device and method for filtering a biological derived sample, such as blood, wherein the device includes a container, a filter, and a fluid flow-through matrix. The filter is used to retain debris in the liquid that would otherwise interfere with an assay for the biological sample. The matrix is used to retain a reagent that interacts in some way with the biological sample. A subsequent reaction surface is utilized with the device and method, wherein the reaction surface contains an immobilized capture reagent (strip of immunochromatographical diagnostic agent) that interacts with the filtered sample, such as through an immunoassay for a sample analyte (see Abstract; column 2, lines 17-24; column 3, lines 2-41; and column 5, lines 9-16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the filter unit of Kitajima et al., Kadoya and Matsuda et al. a reaction surface containing an immobilized capture reagent (strip of immunochromatographical diagnostic agent) as taught by Chu because Chu teaches the benefit of including a reaction surface containing an immobilized capture reagent with a device and method for filtering a biological sample in order to receive and interact with the filtered sample, and to allow for the subsequent immunoassay of a desired sample analyte.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/
Examiner, Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641